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IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -
NIPPON SHINYAKU CO., LTD.,
Plaintiff,
v
SAREPTA THERAPEUTICS, INC.,
Defendant.
- - -
: CIVIL ACTION
:
:
:
:
: NO. 21-1015-LPS

Wilmington, Delaware
Monday, December 20, 2021
Telephonic Oral Argument

- - -
BEFORE: HONORABLE LEONARD P. STARK, U.S.D.C.J.

- - -
APPEARANCES:

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23 P R O C E E D I N G S

24 (REPORTER'S NOTE: The following telephonic oral
25 argument was held in chambers, beginning at 4:15 p.m.)

1 THE COURT: Good afternoon, counsel. This is
2 Judge Stark. Who is there for the plaintiff, please?

3 MS. DUDASH: Good afternoon, Your Honor. This
4 is Amy Dudash from Morgan Lewis, the plaintiff Nippon
5 Shinyaku. And with me on the line also from Morgan Lewis is
6 Amanda Williamson, Krista Venegas, Chris Betti, Maria Ducas,
7 and Zachary Miller. And Ms. Williamson will be presenting
8 argument on plaintiff's behalf today.

9 THE COURT: Okay. Thank you.

10 And who is there for the defendant, please?

11 MR. BLUMENFELD: Good afternoon, Your Honor.
12 It's Jack Blumenfeld from Morris Nichols for Sarepta. We
13 have a number of people on from Finnegan Henderson firm.
14 Mike Flibbert who will be arguing for Sarepta, Charles
15 Lipsey, Aaron Clay, Derek McCorquindale, and Alissa Lipton.
16 And from Sarepta, we have Chris Burney and Jessica Driscoll.

17 THE COURT: Okay. Thank you, and good afternoon
18 to all of you.

19 Brian is here as my court reporter; and for the
20 record, it is our case of Nippon Shinyaku Company, Limited
21 versus Sarepta Therapeutics Inc. It's our Civil Action No.
22 21-1015-LPS. And we are here to hear argument on the
23 defendant's motion to dismiss and/or strike a couple of the
24 claims in the amended complaint.

25 We're going to move pretty quickly. I have

1 allocated about 20 minutes for each side. I do have slides
2 that the plaintiff submitted earlier today, but we'll hear
3 first from the defendant, and I believe that is
4 Mr. Flibbert, and if so, you may begin.

5 MR. FLIBBERT: Thank you, Your Honor. Good
6 afternoon. Mike Flibbert from Finnegan on behalf of
7 Sarepta.

8 THE COURT: All right. Mr. Flibbert, let me
9 interrupt you. It's hard to hear you. I don't know if
10 there is some interference on your side. Try again.

11 MR. FLIBBERT: I'm going to try again, Your
12 Honor.

13 How am I now?

14 THE COURT: It's not much better. Are we on a
15 speaker perhaps?

16 MR. FLIBBERT: How about now, Your Honor?

17 THE COURT: That seems like it might be clearer.
18 Let's go ahead and try that.

19 MR. FLIBBERT: Okay. Let's try that.

20 THE COURT: Okay.

21 MR. FLIBBERT: Thank you, Your Honor. I
22 apologize.

23 If I may, I'd like to start briefly it's our
24 position that Claim 2 should be dismissed under 12(b)(6).

25 Claim 2, Your Honor, of the amended complaint

1 remains facially deficient. Nippon Shinyaku alleges in
2 paragraph 89 that it does not infringe the UWA patents
3 because they are invalid under their position citing the
4 *Commil* case.

5 Your Honor, we have shown this invalidity
6 allegation is insufficient to plead noninfringement under
7 *Commil*. The amended complaint still doesn't identify any
8 facts regarding how Nippon Shinyaku's Viltepso product
9 allegedly doesn't meet one or more limitations of any
10 particular claim of the UWA patent unless it remains
11 facially deficient under *Princeton Digital*.

12 In their opposition brief, Nippon Shinyaku
13 appears to abandon their argument regarding the invalidity
14 allegation, and they don't respond to our point that *Commil*
15 held that invalidity and noninfringement are distinct issues
16 that should not be conflated.

17 In their brief, for the first time in their
18 opposition brief, they raise a new argument that they
19 don't directly infringe any method claim of the UWA patents
20 but, of course, the arguments that are in a brief are not
21 considered in determining the sufficiency of a complaint
22 under, for example, the *Frederico* decision of Third Circuit
23 which we cited.

24 In addition, this new method claim argument
25 only applies to one of the three UWA patents, the '827

1 patent which is Exhibit K to the original complaint, the
2 '851 patent and the '590 patent which were Exhibits I and J
3 to the original complaint, they contain no method claims, so
4 this new argument can't possibly apply to them.

5 THE COURT: All right. Let me stop you. Let's
6 assume I think it's right that I agree with everything you
7 have said to this point just on the 12(b)(6). Do you oppose
8 me giving them leave to amend? Putting aside the subject
9 matter jurisdiction issues, which I'm sure you are going to
10 get to, is it your contention that amendment would be
11 futile?

12 MR. FLIBBERT: We do believe in this situation
13 it is futile because even as to their one patent, the '827
14 that has method claims, there is no allegation that they
15 would not be liable for infringement of that patent under an
16 inducement theory under Section 271(b).

17 THE COURT: Right. But how do we know that they
18 couldn't -- you know, if they're on notice that this doesn't
19 cut it, that they couldn't add a bunch of allegations along
20 the lines you would typically see at least when trying to
21 prove noninfringement?

22 MR. FLIBBERT: Well, I guess, you know, our only
23 response is they haven't done so even in their briefs, Your
24 Honor. They could have, you know, they could have raised
25 it at least in their brief, and they haven't done that.

1 THE COURT: Okay.

2 MR. FLIBBERT: I understand it's a question of
3 Your Honor's discretion in terms of amendment.

4 THE COURT: Okay. Do you want to move on to
5 some of the other issues?

6 MR. FLIBBERT: Yes, Your Honor. So for the
7 subject matter jurisdiction, we submit that they have failed
8 to establish a case or controversy under the totality of the
9 circumstances test of *MedImmune*, and it's undisputed here
10 that when the MCA covenant term ended, Sarepta did not sue
11 Nippon Shinyaku for infringement of the UWA patents, and it
12 still has not done so.

13 Instead, Sarepta only filed IPR petitions with
14 the patent challenging the patentability of the Nippon
15 Shinyaku patents, different patents. And Sarepta took that
16 action to protect its freedom to market its Vyondys 53 drug
17 product which is used to treat children in a particular form
18 of Duchenne muscular dystrophy.

19 Now, Nippon Shinyaku is seeking to establish
20 jurisdiction here based largely on the parties' confidential
21 business discussions under the MCA, and we have moved to
22 strike the confidential material.

23 In *SanDisk*, of course, the Federal Circuit
24 stated that to avoid the risks of a D.J. action, parties may
25 agree to a suitable confidentiality agreement. And that is

1 precisely what the parties did here, Your Honor. They
2 agreed to broad obligations of confidentiality and nonuse in
3 Section 2 of the MCA.

4 And the nonuse provisions of Section 2.2, for
5 example, provide that all disclosures including all
6 meetings, discussions and communications between the
7 parties in connection with the agreement and the proposed
8 transaction shall not be submitted, referenced, or otherwise
9 used against the other party in any legal action except the
10 inaction to enforce the terms of the agreement.

11 And these provisions of confidentiality and
12 nonuse of Section 2 remain fully in effect under Section 7
13 and 12 of the MCA.

14 THE COURT: All right. But of course -- I'm
15 sure you are getting there. We don't have a lot of time.
16 They say is an action for enforcement. And I think you
17 concede it is an action for enforcement at least with
18 respect to Count 1, so why aren't they right that that opens
19 the door to them using this confidential information however
20 they want in this action for enforcement?

21 MR. FLIBBERT: Right. For a couple of reasons,
22 Your Honor.

23 First, their breach of contract claim concerns
24 the interpretation of a forum selection clause which
25 involved entirely distinct facts from the D.J. claims. The

1 parties' confidential communications under the MCA are
2 irrelevant to the forum selection clause issues. And, for
3 example, the amended complaint does not substantively rely
4 on any of those confidential communications in addressing
5 the forum selection cause.

6 As you will also recall, they didn't rely on any
7 of those communications previously in their preliminary
8 injunction briefing as well when they were arguing for
9 reasonable likelihood of success. They never referred to
10 any of those communications. So that shows, first of all,
11 that they're irrelevant.

12 The second point is that under their position,
13 that would allow the use of this confidential information in
14 any case as long as it was contained in the same complaint
15 as the breach of contract claim, but that is not what the
16 claim language says. This is a narrow exception that is
17 only intended to support the enforcement of contract rights
18 under the MCA. And I think importantly, it was intended
19 to make the confidentiality and nonuse obligations more
20 enforceable, not less enforceable. Their position would
21 essentially gut this provision and render it meaningless
22 because you could simply append a contract claim to an
23 action and avoid these protections.

24 We don't think that that is what was intended.
25 We think it was intended to make this, these obligations of

1 confidentiality and nonuse more enforceable, not less
2 enforceable.

3 They also point to Claims 2 and 3 and they
4 argued that those claims themselves are actions to enforce
5 the forum selection clause, and we disagree with that as
6 well.

7 The D.J. claim seeks highly different relief
8 from Claim 1, the breach of contract claim. So we don't
9 think that is a reasonable argument.

10 THE COURT: Might you -- yes. Just might you
11 have a claim for breach of the MCA against them based on
12 what you contend is a violation of 2.2?

13 MR. FLIBBERT: Yes, there could be. There
14 could be possibly a breach of the MCA based on their action,
15 but that wouldn't allow them to use this information to
16 establish unrelated D.J. claims. You know, that was not the
17 purpose of the exception.

18 The exception -- an example where the exception
19 was intended to apply would be, for example, if a party had
20 sales information that they had disclosed confidentially and
21 it was, you know, publicized, this confidential information
22 was publicized, and then a breach of contract action had to
23 be filed. Well, of course, you would have to refer to the
24 parties exchange of confidential information in order to
25 enforce that breach. Enforce the contract.

1 So that again is intended to strengthen the
2 confidentiality and nonuse protection, not weaken it, which
3 is what their position would essentially do.

4 THE COURT: On the subject matter jurisdiction
5 question though, I have an independent obligation to
6 evaluate whether this court has case or controversy, has
7 subject matter jurisdiction.

8 I know the parties can't create jurisdiction
9 where it doesn't exist, but wouldn't your interpretation
10 of the MCA here potentially allow parties to destroy
11 jurisdiction where it otherwise exists? That is, you have
12 a breach of contract claim because maybe they have misused
13 the confidential information but they put the confidential
14 information in front of me. Let's just say for the sake of
15 argument I think it shows you are about to sue them. You
16 know, maybe I never should have heard that but I did. Can I
17 just ignore that because it's a violation of a contractual
18 obligation when it's a fact in front of me?

19 MR. FLIBBERT: I think that goes right to the
20 prejudice, Your Honor. I mean they argued they haven't been
21 prejudiced, but of course it has. Because Your Honor now
22 has heard this information. And, yes, essentially what
23 we're asking is for Sarepta to be placed in the position it
24 would be in but for the breach. That the information should
25 be excised from the complaint, and Your Honor should not

1 consider it in weighing the facts and using Your Honor's
2 discretion in evaluating the D.J. question.

3 It goes right to the prejudice. And that is
4 why there is prejudice here, because they have disclosed
5 this information. And it's really unfair when the D.J.
6 jurisdiction issue will be evaluated in the context of
7 information that never should have been provided to the
8 Court in this briefing.

9 And that's why, you know, that's why we think it
10 is appropriate to strike the information and reevaluate the
11 D.J. jurisdiction issue without that information that should
12 not have been used that was subject to confidentiality under
13 the MCA.

14 THE COURT: Okay. You can move on if there is
15 anything else you wanted to cover.

16 MR. FLIBBERT: A couple of, a couple of points,
17 Your Honor.

18 So we do believe, for example, in paragraph 2,
19 the second sentence, paragraphs 11, 78 and 91, those
20 paragraphs all directly disclose the substance of the
21 parties' discussions under the MCA and should be stricken.

22 Paragraphs 18, 85, and 98 disclose the outcome
23 of the parties' confidential negotiations, not leading to
24 the grants of the license or covenant not to sue and
25 therefore we also submit they improperly disclose the

1 substance of the negotiations. These are not purely factual
2 statements, which is what Nippon Shinyaku argues. These are
3 paragraphs that refer to the outcome of the negotiations and
4 should be stricken.

5 We do maintain that the pre- and the
6 post-communications should be protected under the MCA for a
7 couple of reasons:

8 One is that Section 2.2 is quite broad in its
9 language, and it's not time bound in terms of with respect
10 to the term of the MCA, and we believe that the pre- and the
11 post-communications should also have the benefit of that
12 protection.

13 But I also wanted to point out that with regard
14 to the post-MCA communications, and, for example, the email
15 from Mr. Zanca from July 6th, maybe even that should be
16 protected because if you look at the documents, they show
17 that the parties continue to treat their communications
18 after the MCA expired as confidential.

19 As an example of that, Mr. Toda, in his June
20 14th email to Mr. Zanca, said: "Thank you for your
21 confirmation regarding confidentiality and evidentiary
22 privilege." And there is a redaction. Then it says, "We
23 look forward to hearing from you."

24 And we submit that his statements created an
25 expectation that Mr. Zanca's response would also be treated

1 as confidential. So we believe that the July 6th email
2 should be treated as confidential based on the parties
3 agreement to extend this confidentiality treatment for some
4 continued discussions after the MCA tender.

5 Now, we also -- but beyond the fact that we
6 think these statements should be stricken, the pre- and
7 the post-communications, we don't think that they establish
8 D.J. jurisdiction.

9 The pre-MCA communications only establish that
10 the parties are only interested in discussing the possible
11 cross-licensing that Sarepta, and the post-MCA
12 communications similarly do not only establish jurisdiction,
13 and turning back again to this July 16th email from Mr.
14 Zanca, the email only identifies the NS patents that were
15 challenged by Sarepta in their IPR petitions filed with
16 the board. There is no mention of the UWA patents in that
17 email.

18 Now, there is reference to other actions, but
19 those other actions could have referred to various other
20 actions, such as the EP oppositions and Japanese actions
21 that aren't mentioned in the MCA.

22 So there are other actions that the parties have
23 been discussing, European and Japanese proceedings, so it
24 is just as likely he was referring to that, and there is no
25 reference to enforcement of the UWA patent against Nippon

1 Shinyaku in that email even if Your Honor does consider it.

2 THE COURT: All right. But it seems to me
3 that what you are arguing is a reasonable inference of
4 the parties' course of communications but not the only
5 reasonable inference. Isn't it enough for the plaintiff
6 today that I can say one might reasonably think from this
7 course of conduct and communications that it's plausible
8 that you were asserting your patents or that you would
9 imminently do so? I can't eliminate that possibility or
10 even come close to it on this record, can I?

11 MR. FLIBBERT: Well, one other point on the
12 Zanca email. As I said, we believe that it's not
13 appropriate to consider the outcome of these negotiations,
14 and that is really what they're seeking to do with the Zanca
15 email. They're seeking to have Your Honor conclude that the
16 negotiations failed and therefore there was a possibility of
17 infringement litigation.

18 But again, they should not be permitted to use
19 any information to suggest that the negotiations were
20 unsuccessful, including the Zanca email. That is precisely
21 what the parties were trying to prevent with the MCA.

22 THE COURT: All right.

23 MR. FLIBBERT: Now, in terms of --

24 THE COURT: Yes, I would like to save your last
25 four minutes for rebuttal.

1 MR. FLIBBERT: Yes, Your Honor.

2 THE COURT: So let me stop you there.

3 MR. FLIBBERT: Thank you very much.

4 THE COURT: And I will turn to Ms. Williamson at
5 this point.

6 MR. FLIBBERT: Thank you.

7 MS. WILLIAMSON: Thank you, Your Honor. This is
8 Amanda Williamson from Morgan Lewis on behalf of Nippon
9 Shinyaku --

10 THE COURT: Good afternoon.

11 MS. WILLIAMSON: -- the plaintiff in this case.
12 And I would like to touch on a point that Your Honor has
13 raised.

14 The manner in which Sarepta is seeking to
15 interpret the MCA is essentially creating a permanent
16 covenant not to bring a declaratory judgment action against
17 Nippon Shinyaku, particularly as they apply the preclusion
18 against disclosure of information to all statements before
19 the MCA was enacted and anything that occurred afterward,
20 after it clearly had terminated.

21 Such a permanent preclusion of a declaratory
22 judgment is actually, it's inconsistent with the covenant
23 not to sue that the parties actually negotiated in Section 6
24 of the MCA which we have in Slide 7. And in the covenant
25 not to sue, the term is expressly limited to 21 days after

1 the expiration of the MCA.

2 But by Sarepta's reading, we are precluded from
3 all time from alleging any facts in support of declaratory
4 judgment.

5 And just by way of an example, under this
6 reading, Sarepta could send Nippon Shinyaku a letter
7 demanding payment of \$15 million and threatening to assert
8 the UWA patents tomorrow, and we still would have no
9 recourse because we would be precluded from raising those
10 facts with Your Honor.

11 We think that far exceeds any time period
12 contemplated by the parties in terms of a covenant not to
13 sue.

14 THE COURT: Go ahead.

15 MS. WILLIAMSON: We also, we also believe that
16 the MCA, as Your Honor raised, specifically permits the use
17 of information in an action to enforce the terms of this
18 agreement. And there is really no dispute that Claim 1 is
19 a properly pled claim for breach of contract, and that
20 Sarepta has identified no grounds for its dismissal.

21 There is also no case law suggesting that this
22 Court can strike or disregard allegations that are properly
23 plead in the complaint when they're used to support additional
24 counts such as Counts 2 and 3.

25 We also believe that Counts 2 and 3 for

1 declaratory judgment of noninfringement and invalidity are
2 claims to enforce the terms of the MCA. As Your Honor
3 pointed out, had we -- had Nippon Shinyaku sued in another
4 District, Sarepta would have had a claim for breach of that
5 agreement. And we see no substantive argument as to why the
6 Counts 2 and 3 are not counts to enforce the MCA.

7 THE COURT: Let me just ask you -- yes. On 2.2,
8 respond to Sarepta's contention that you basically are
9 taking a narrow provision that narrowly allows some use of
10 confidential information and you are making it so broad that
11 it basically becomes a nullity.

12 While I understand you say Count 1 is properly
13 pled, I'm not clear on what would prevent you from arguing
14 that we could file even a frivolous breach of contract claim
15 and then use all the confidential information for any other
16 claim that we just want to put in the same action. Could
17 you respond to that?

18 MR. FLIBBERT: Sure, Your Honor. I do think
19 that Sarepta is reading Section 2.2 far too broadly. And
20 that I don't believe that an exception allowing these facts
21 to be plead a breach of contract claim would open up the
22 field as they have described.

23 This is -- Nippon Shinyaku's claim is not a
24 frivolous claim. We have been before Your Honor and Your
25 Honor has disagreed with our theory is breached, but it was

1 not frivolous and not intended merely as some sort of hoax
2 to then raise additional declaratory judgment.

3 THE COURT: Right. But wouldn't your view -- I
4 mean we can stipulate to that for purposes of today, that's
5 fine, but wouldn't your view of 2.2 allow you to file a
6 frivolous breach of contract claim to open the door to use
7 all the confidential information in a way that clearly was
8 not intended in the MCA?

9 MS. WILLIAMSON: Well, I don't think we would
10 ever be permitted to file a frivolous claim. We would have
11 to have a legitimate basis to bring the claim in the first
12 place.

13 But even if Your Honor were to find that we
14 cannot rely on certain of the confidential information,
15 which we believe could only apply to what is basically
16 paragraph 11, and the subsequent MCA-related paragraphs in
17 the complaint that Sarepta has moved to strike. Outside of
18 the direct statements from the negotiation, we believe that
19 Nippon Shinyaku has pled sufficient facts to establish
20 declaratory judgment jurisdiction.

21 THE COURT: Okay. Did you want to say more on
22 the jurisdictional stuff or is that it?

23 MS. WILLIAMSON: Sure. For the non-MCA
24 complaints, including paragraphs 15 through 21, those
25 relate to pre- and post-MCA activities and are not -- are,

1 they're sufficient to establish declaratory judgment.

2 If Your Honor would turn to Slide 5 in the
3 presentation we prepared for the Court, we have provided
4 the preamble to the MCA. And what the preamble says very
5 clearly is that it talks about the parties wishing to enter
6 into discussions concerning the proposed transaction.

7 According to the preamble, discussions between the
8 parties before the MCA was negotiated or after it terminated
9 would not relate to this period or the contractually defined
10 proposed transaction and should not be protected by the MCA.

11 So if you turn to Slide 6 in our presentation
12 where we have Section 2.2, it sets further limits on
13 confidential information to those things being exchanged
14 between the parties made in connection with this agreement
15 and the proposed transaction. It is our view that the
16 proposed transaction was not evaluated, did not begin
17 until the MCA was executed and was terminated on the
18 termination date of June 1st, 2021 when Sarepta refused to
19 extend the term to further negotiate under the terms of
20 the MCA.

21 So turn to Slide 11. Paragraph 15 at -- 17 of
22 the first amended complaint alleged that by January 2020,
23 Sarepta informed Nippon Shinyaku that a license to the UWA
24 patent was necessary for Nippon Shinyaku to avoid litigation
25 regarding Viltepso.

1 This is a statement of fact, and it is a
2 statement of nonconfidential information that occurred
3 before the UWA -- I'm sorry -- before the MCA was executed.

4 These paragraphs of our complaint also summarize
5 the pre-MCA communication that were not confidential stating
6 that the parties agree to engage in negotiations concerning
7 their potential patent portfolio and that Nippon Shinyaku
8 understood that the purpose of the discussion was to avoid
9 litigation. And as Your Honor made notice, Sarepta does not
10 dispute the veracity of Nippon Shinyaku's well-pled facts.

11 It does not state that Sarepta has no intent to
12 sue Nippon Shinyaku. There have been two points in time
13 where Nippon Shinyaku has attempted to negotiate and enter
14 into covenants not to sue, first with the MCA in June of
15 2020 and then again in September. And Sarepta continued to
16 withhold its agreement not to sue Nippon Shinyaku and leave
17 the continual threat of litigation over the UWA patents for
18 our client.

19 Paragraph 18, Your Honor, which is shown on
20 Slide 12, is also a statement of fact and not based on
21 communications that they -- that the parties are no longer
22 engaged in confidential discussions.

23 We really don't see how Sarepta can include the
24 termination of negotiations as a piece of confidential
25 information. It's pretty clear that there is no longer any

1 discussion over licensing going on between the parties as
2 evidenced by a breach of contract suit and also our Nippon
3 Shinyaku complaint for patent infringement and declaratory
4 judgment.

5 With respect to Mr. Toda's email. In that
6 exchange, Nippon Shinyaku requested that a specific post-MCA
7 offer be provided, be taken as confidential information.
8 Nippon Shinyaku's understanding was that without a specific
9 designation, the parties' communication were no longer
10 confidential because the MCA would have been no longer in
11 effect.

12 That was evidenced -- the termination of the
13 MCA and its preclusions was then subsequently evidenced when
14 Sarepta filed its seven IPR petitions, which had there been
15 an extension of any provision under the MCA, it would also
16 have also included the covenant not to sue, which clearly
17 Sarepta viewed was not in effect at that time.

18 So as for Nippon Shinyaku, Nippon Shinyaku did
19 not believe that there was any confidentiality provisions
20 that continued after the end of the MCA.

21 THE COURT: And am I right that as long as that
22 is a reasonable interpretation of the evidence that you all
23 have put in front of me, that you did not think that the
24 confidentiality obligations continued beyond the expiration
25 of the MCA, that is all you need to prevail on the relevant

1 portions of the motion today?

2 MS. WILLIAMSON: I'm sorry, Your Honor. Could
3 you repeat that question?

4 THE COURT: Sure. I mean I'm basically asking
5 am I sitting as a fact finder on what is the right
6 interpretation of the email and the various communications
7 about confidentiality or is it enough if you just sort of
8 made a plausible, reasonable argument from that evidence?

9 MS. WILLIAMSON: Yes, Your Honor. Sarepta's
10 challenge is entirely facial. They have not challenged
11 Nippon Shinyaku's interpretation of the facts as pled in
12 the complaint.

13 We believe as long as that interpretation is
14 reasonable, it properly supports declaratory judgment, and
15 Sarepta is really making no argument to the contrary. Their
16 argument is limited to their motion to strike and your
17 ability to consider all those facts that we have pled, not
18 that those facts are incorrect or mischaracterize the
19 parties beliefs or the situation that would -- the situation
20 in suit between the parties.

21 THE COURT: Okay. Let's come to, I guess it's
22 Count 2, for declaratory judgment of noninfringement.

23 Have you abandoned the theory that it's
24 sufficient to say we don't infringe because the patent is
25 invalid or is that still an argument you are pressing?

1 MS. WILLIAMSON: Your Honor, we haven't
2 abandoned that argument, but we appreciate the case law that
3 Sarepta has identified. We believe our allegations as in
4 the first amended complaint are sufficient to put Sarepta
5 notice of our claims of infringement.

6 We also believe we have sufficiently alleged the
7 facts with respect to the indirect infringement that were
8 discussed earlier.

9 If Your Honor feels that our pleading has fallen
10 short, we would request leave to amend, and we believe we
11 could do so to sufficiently satisfy the Court.

12 THE COURT: You cite, among others, this
13 *Rain Gutter* decision, I think it's Western District of
14 Washington, which says in effect: When the plaintiff has
15 identified one of its products and the claim elements
16 from the asserted patents it believes are missing, the
17 noninfringement declaratory judgment claim is sufficiently
18 pled.

19 But I'm not seeing where you identify the claim
20 elements that are missing from your product. Did I miss
21 that?

22 MS. WILLIAMSON: No, Your Honor. I don't think
23 we pointed to any of the specific elements. Just the
24 general statement with respect to the product.

25 THE COURT: And so this is an amended complaint,

1 so it's already your second try. I recognize I have a lot
2 of discretion here, but why should I give you a third chance
3 to basically do that?

4 MS. WILLIAMSON: Well, we believe we can correct
5 the deficiencies in the claim. And we would respectfully
6 ask for permission to do so.

7 THE COURT: Okay. Is there anything else,
8 Ms. Williamson?

9 MS. WILLIAMSON: It's also very early in the
10 case, and long before discovery has even started. So we
11 don't feel that there would be any prejudice to Sarepta
12 for allowing us an additional attempt to amend the claim.

13 THE COURT: All right. Is there anything else
14 you want to add?

15 MS. WILLIAMSON: No, that's all. Thank you,
16 Your Honor.

17 THE COURT: Thank you.

18 Mr. Flibbert, back to you.

19 MR. FLIBBERT: Thank you, Your Honor.

20 With regard to the exception, again I just
21 wanted to emphasize that Nippon Shinyaku has never used any
22 of the confidential information that they support in the
23 complaint. They never used that to support the forum
24 selection clause argument. There is nothing in the amended
25 complaint that refers to any of that information in

1 connection about the forum selection issue.

2 And during the briefing on the preliminary
3 injunction issue, we never referred to any of that issue.
4 So we believe it is simply irrelevant to Claim 1, and it's
5 not been used to support Claim 1.

6 We also, you know, we disagree with their
7 argument that we're asking for incredibly broad
8 interpretation or that it goes beyond the claim language.
9 The plain language really shows this is a narrow exception
10 that is intended to support and strengthen the contract
11 rights that are set forth in Section 2.2. It's intended to
12 make the confidentiality and nonuse obligations more
13 enforceable, more legally enforceable, not less enforceable
14 which is what they are trying to do.

15 In terms of the pre- and the post-MCA
16 communications, there is no allegation -- we agree we have
17 to, we're looking at this on the face of the pleadings, but
18 there is no allegation that Sarepta ever raised the UWA
19 patents specifically either before or after the MCA.

20 So they talk about at their own subjective fear
21 about the UWA patents but that is insufficient under the
22 case law. What is relevant is whether Sarepta affirmatively
23 raised the UWA patents with them, and I don't believe they
24 actually have any allegations that Sarepta specifically
25 referred the UWA patents either pre- or post-MCA.

1 We DO believe obviously the discussions before
2 the MCA should be stricken, but there is no, I don't
3 believe, any UWA patents on the pre- and post-MCA.

4 On the covenant not to sue issue, we cited
5 the *Microsoft vs. DataTern* case from the Federal Circuit
6 which held that, "Decline to grant the covenant to sue is
7 not sufficient to create an actual controversy because
8 the patentee has no obligation to make a definitive
9 determination at the time and place of the competitor's
10 choosing, that it will never bring infringement suits. And
11 I don't believe they responded to that case.

12 In terms of their other obligation with regard
13 to the alleged targeting of the UWA claims of their product,
14 in paragraph 14, the very next sentence in that allegation,
15 in that paragraph acknowledges that the UWA patents cover
16 Sarepta's product, the Vyondys 53 product, and therefore it
17 is logical for Sarepta to list those patents in the Orange
18 Book to protect its own product.

19 So again, just looking at the face of this
20 complaint, if the confidential information is removed, as we
21 believe it should be, we don't think there will be
22 sufficient pleading facts -- pled facts to establish a case
23 or controversy at that point.

24 So that's in terms of the -- and I guess there
25 is a finding on the D.J. issue. There was again a reference

1 to paragraph 18. As I said, we disagree that that is a
2 factual statement. That paragraph expressly refers to the
3 outcome of the negotiation which should not be disclosed.

4 Just as if, for example, Your Honor were to --
5 you know, if someone were to tell you what was the outcome
6 of a confidential mediation, you wouldn't expect that that
7 would be disclosed to you; right? So it's similar to that.
8 The outcome of the negotiation should not have been
9 disclosed in the amended complaint.

10 THE COURT: Okay. I'm going to have to stop you
11 there. Your time is up. But thank you very much,
12 Mr. Flibbert and Ms. Williamson, for the helpful argument.

13 MR. FLIBBERT: Thank you.

14 THE COURT: I'm going to give you my decision
15 now on the motion. It's Sarepta's motion to strike and
16 dismiss relating to Claims 2 and 3 of the amended complaint
17 by Nippon Shinyaku who I may refer to as "NS" as I go along.

18 The motion is granted in part and denied in
19 part. And I'll have to explain to what extent each of those
20 is applicable, and I will aim to do so as I go through.

21 First, on the legal standards, I think there is
22 not any real dispute about what standards apply. The Rule
23 12(b)(6) standard is well settled. There is no dispute on
24 that.

25 On the motion to strike Rule 12(f) which we see

1 less frequently than 12(b)(6) motions, of course, that rule
2 permits the Court, in its discretion, to strike from a
3 pleading any redundant or scandalous matter. These motions
4 are generally not favored, but courts have recognized that
5 they may be appropriate vehicles to strike allegations that
6 are made in violation of the confidentiality agreement which
7 is the basis for the motion here.

8 In terms of Rule 12(b)(1), motions to dismiss
9 the Court can, and indeed must, dismiss if it lacks subject
10 matter jurisdiction.

11 Here, what is at issue is the declaratory
12 judgment claim. In order for me to have jurisdiction over a
13 declaratory judgment claim, I must have a justiciable case
14 of actual controversy, and the test under *MedImmune* from the
15 Supreme Court in 2007 is essentially to consider whether the
16 facts alleged under all the circumstances show that there is
17 a substantial controversy between parties having adverse
18 legal interest of sufficient immediacy and reality to
19 warrant the issuance of a declaratory judgment.

20 So with that background, law, let me turn to the
21 various arguments in the portions of the motion.

22 So first, there is a motion to dismiss Claim 2
23 under 12(b)(6) for failure to state a noninfringement claim.

24 And this portion of Sarepta's motion is granted
25 as I agree with Sarepta that the allegations as pled in the

1 amended complaint are insufficient to state a claim of
2 noninfringement. Consistent with Rule 8(a), Claim 2
3 contains really only a single paragraph regarding NS's
4 noninfringement theory. To the extent that theory is still
5 a theory that, hey, we don't infringe because your patent is
6 invalid, that is not adequate to state a declaratory
7 judgment claim of noninfringement.

8 *Commil* makes clear when infringement is the
9 issue, the validity of the patent is not the question to be
10 confronted. And the parties, at least the defendant, that
11 is, cites cases in a context very much like this one which
12 make clear that what the plaintiff has attempted to do, to
13 the extent again they're relying on invalidity, is not
14 adequate.

15 Further, and I think it's essentially conceded
16 today, the amended complaint does not point to any facts
17 regarding how NS's product does not meet one or more
18 limitations of any particular claim of the defendant's
19 patents.

20 There is a suggestion in the briefing from the
21 plaintiff that it does not directly infringe method claims
22 because it's a manufacturer and a marketer and not a
23 physician, but a complaint can't be amended by the briefing
24 on the motion to dismiss. And anyway, at best this might
25 state a claim, this theory, that is, if it were in the

1 complaint, might state a claim for a declaratory judgment
2 of noninfringement with respect to direct infringement, but
3 the cases that the plaintiff relies on to say that that
4 therefore would give me -- you know, that they have stated
5 adequately a claim that would give me jurisdiction to
6 resolve all infringement issues under all three patents and
7 all three claims -- in all of the claims of those patents
8 under direct and indirect theories, I don't think any of the
9 cases the plaintiff cited read that broadly.

10 I will, however, subject to what I'm about to
11 say next on the rest of the motion, I will grant leave to
12 amend this Claim 2. The plaintiff has asked for that leave.
13 It is early in this case, even though quite a lot has
14 happened for an early stage case like this one.

15 I don't think there is any real prejudice to the
16 defendant to giving the plaintiff what will be its third
17 chance, but giving them leave to amend. I think that is
18 consistent with the liberal approach to amendments in the
19 Third Circuit as embodied in Federal Rule of Civil procedure
20 15.

21 Let me turn, though, to the motion to strike.
22 And there, I'm going to divide my analysis between the
23 so-called MCA paragraphs and the non-MCA paragraphs.

24 I'll start with the MCA paragraphs which I
25 understand to be the second sentence of paragraph 2 as well

1 as paragraphs 11, 78, and 91 of the amended complaint.

2 Here, the plaintiff NS argues that it may rely
3 on confidential communications made during the term of the
4 agreement because of the exception in Section 2.2. And the
5 exception is excerpted in the briefing and it's in the
6 plaintiff's slides. We talked about it.

7 Basically, I do not agree with NS's reading
8 of Section 2.2. NS says it's a general prohibition against
9 mentioning confidential communications in legal actions but
10 does not apply here because this case is, in NS's view, an
11 action to enforce the terms of the agreement.

12 In my view, that reading would allow what is I
13 think intended to be and I think is on the language a narrow
14 exception, that is, a narrow exception to the prohibition on
15 use of confidential communications made during the effective
16 period of the MCA. The plaintiff's interpretation of that
17 narrow exception would be so broad as to essentially swallow
18 all of it.

19 As Sarepta I think persuasively explains, NS's
20 interpretation would allow the parties' confidential
21 information to be used in any claim at all so long as it is
22 contained in the same complaint as a breach of contract
23 claim even if that breach of contract claim lacked merit.

24 And I agree with Sarepta that that is the import
25 of the plaintiff's interpretation. And I think it's wrong.

1 It's not consistent with the plain language of 2.2, and it's
2 not consistent with the intent of the parties in entering
3 into the MCA.

4 Moreover, I think NS is wrong to view claims 2
5 and 3 as seeking to enforce the terms of the mutual
6 confidential agreement. Instead, claims 2 and 3 seek
7 declaratory judgments of noninfringement and invalidity of
8 the defendant's UWA patents. They have nothing to do with
9 legal obligations imposed by the mutual confidentiality
10 agreement.

11 In other words, and relatedly, NS is not seeking
12 by its declaratory judgment claims in claims 2 and 3 to
13 enforce the forum selection clause by pursuing claims 2 and
14 3. It's merely I suppose arguably complying with its view
15 of the forum selection clause, but in my view, that is
16 quite different than being an action to enforce the forum
17 selection clause or an action more broadly to enforce the
18 MCA.

19 So I don't think -- so I'm granting this portion
20 of the motion. Permitting NS to violate the confidentiality
21 agreement and use confidential communications between the
22 parties to support Claims 2 and 3 would unfairly prejudice
23 Sarepta which bargained for these communications not to be
24 used except in a cause of action seeking to enforce the
25 parties' agreement.

1 NS agreed not to hold the parties' confidential
2 communications against Sarepta in future litigation such
3 as litigation like a declaratory judgment claim of
4 noninfringement, but now NS is trying to do exactly that,
5 and that cannot be permitted under the terms of the MCA.

6 So the Court will strike the MCA paragraphs to
7 the -- so I will strike those.

8 Let me now turn to the non-MCA paragraphs. And
9 by that, I mean paragraphs 15 to 21, 82 to 88, and 95 to 101.

10 Again, the relevant provision of the mutual
11 confidentiality agreement is Section 2.2 which applies to
12 all disclosures made in connection with this agreement and
13 the proposed transaction.

14 In Sarepta's view, statements made before the
15 MCA became effective and statements made after its term
16 expired still fall within Section 2.2 because they were
17 related to and, therefore, made in connection with the
18 agreement.

19 In my view, Sarepta is interpreting this aspect
20 of Section 2.2 too expansively. All disclosures made in
21 connection with this agreement and the proposed transaction
22 in my view more naturally refers to disclosures of
23 confidential information as defined in the agreement. The
24 agreement defines confidential information as certain
25 information disclosed during the term of the MCA.

1 There is no dispute about that. That the
2 agreement didn't begin until June 1st, 2020, and it ran for
3 a year. Accordingly, in my view, NS is free to rely on
4 communications that occurred before the MCA's term started;
5 that is, before June 1st, 2020. And so I'm not going to
6 strike the non-MCA paragraphs. I'm not going to strike the
7 ones from before the MCA was in effect. And likewise, I'm
8 not going to strike the ones that is the communications made
9 after the confidentiality agreement ended.

10 With respect to that latter period after the MCA
11 ended, I recognize that Sarepta argues the parties voluntarily
12 agreed to extend their confidentiality obligation, but the
13 record leaves doubts in my mind on that point.

14 There is an email to NS in which Sarepta
15 confirmed that any response that it receives from NS by a
16 date in June to Sarepta's term sheets in May will constitute
17 confidential information under the MCA.

18 That statement at least arguably encompasses
19 communications from NS to Sarepta but it does not explicitly
20 cover communications from Sarepta to NS.

21 Further, there is evidence that Sarepta
22 suggested possibly extending the MCA agreement by signing
23 an amendment which indicates that Sarepta was aware that
24 the confidentiality provisions did not yet apply to future
25 communication. And, moreover, NS's response to Sarepta,

1 thanking it for its confirmation regarding confidentiality
2 and evidentiary privilege is, in my view, vague.

3 And all of that I think is important given the
4 early stage we're at. Typically, any doubt that exists on a
5 motion to strike under Rule 12(f) should be resolved in the
6 nonmovant's favor, and I'm doing that here.

7 So, again, the Court will not strike the
8 allegations concerning communications made after the MCA's
9 term ended, nor will it strike allegations concerning
10 communications made before the MCA ever took effect.

11 Finally, let me just quickly address the motions
12 to dismiss, to the extent it arises under Rule 12(b)(1). I
13 have to consider whether the remaining allegations, that is,
14 those I haven't stricken in the amended complaint, are
15 sufficient to establish subject matter jurisdiction for
16 Claims 2 and 3.

17 And I find that they are.

18 For instance, paragraphs 15 to 17 of the amended
19 complaint which has not been stricken, I must, of course,
20 accept the factual allegations in what I haven't stricken to
21 be true.

22 Paragraph 15, for example, states that Sarepta
23 and NS have engaged in nonconfidential communications
24 regarding the licensing of Sarepta's UWA patents.

25 Paragraph 16 provides a specific example of a

1 conversation between the two parties where allegedly NS
2 understood future confidential discussions would include
3 discussions of licensing Sarepta's patents to avoid
4 litigation.

5 Paragraph 17 alleges that only a few weeks
6 later, representatives from both parties had a discussion in
7 which Sarepta raised concerns about the possibility of
8 litigation.

9 Sarepta's participation in licensing discussions
10 regarding its UWA patents I think is conduct that can be
11 reasonably inferred as demonstrating an intent to enforce
12 the UWA patents. That standard, in part, is reflected in
13 the Federal Circuit's *Hewlett Packard* decision.

14 In other words, there is a significant risk that
15 Sarepta will accuse NS of infringement potentially exposing
16 NS to liability. It may be that Sarepta is right on the
17 merits that this evidence will prove merely that the parties
18 were working together to avert controversy.

19 There are all sorts of inferences that the
20 defendant asked me to draw. They're set out particularly at
21 pages 16 to 17 of the opening brief. Those may well be
22 reasonable inferences from the limited record I have in
23 front of me, but the contrary inferences that the plaintiff
24 asked me to draw, namely, that we reasonably fear and an
25 objective observer would think that Sarepta may be about to

1 immediately sue us on the UWA patents. Those are also at
2 least equally reasonable and plausible inferences on the
3 record before me.

4 So on the whole, considering the record, I
5 conclude that NS has shown there is a substantial
6 controversy of sufficient immediacy and reality to warrant
7 the issue of a declaratory judgment. Therefore, to the
8 extent the motion arises under 12(b)(1), it is denied.

9 So where that leaves us is the plaintiff has to
10 file another amended complaint because I have stricken parts
11 of the operative amended complaint. And plaintiff has leave
12 to further amend, if it wishes, and believes that it can
13 correct the pleading deficiencies I have identified
14 consistent with Rule 12(b)(6). Whatever amended complaint
15 the plaintiff is going to file has to be filed no later than
16 January 20th of next year.

17 That was all I had to say. I don't want any
18 further argument, but let me see if you have any questions
19 for me.

20 First, Mr. Flibbert?

21 MR. FLIBBERT: No questions. Thank you, Your
22 Honor.

23 THE COURT: Thank you. And Ms. Williamson?

24 MS. WILLIAMSON: No questions. Thank you, Your
25 Honor.

1 THE COURT: Okay. Thank you all very much.
2 Happy holidays, stay safe, and we are in recess. Thank you.
3 Bye-bye.

4 (Telephonic oral argument ends at 5:13 p.m.)
5

6 I hereby certify the foregoing is a true and accurate
7 transcript from my stenographic notes in the proceeding.

8 /s/ Brian P. Gaffigan
9 Official Court Reporter
10 U.S. District Court
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